REMARKS

Prior to this amendment, Claims 43-49, 51-56, and 58-64 were pending in this application. Claim 49 is amended herein. No new claims are added or cancelled. Accordingly, Claims 43-49, 51-56, and 58-64 remain pending for reconsideration.

Claims 43, 44, 48, 49, 51-56, And 58-64 Are Patentable Over Daniel And Guenther

Claims 43, 44, 48, 49, 51-56, and 58-64 are rejected in the Office Action under 35 U.S.C. § 103(a) as being unpatentable over Daniel et al. (U.S. Patent No. 6,001,118) in view of Guenther et al. (5,102,415). The Examiner notes that Daniel fails to teach or suggest at least the limitations of Claims 44 and 55 related to interrupting fluid flow and occluding blood flow, and a size limitation set forth in dependent Claim 56. The Examiner asserts that the size limitation of Claim 56 would have been an obvious matter of design choice. The Examiner also asserts that the braid structure with outer coating of Guenther meets the limitations related to interrupting fluid flow and occluding blood flow. However, the Examiner fails to identify a motivation for combining Daniel and Guenther.

Applicants respectfully submit that there is no motivation to combine these references and that the combination of these references is improper. For at least these reasons, the Examiner has failed to establish a prima facie case of obviousness. Therefore, these claims are not properly rejected under 35 U.S.C. § 103(a).

The Combination Of Daniel And Guenther Is Improper

As noted above, the Examiner does not set forth a motivation for combining Daniel and Guenther. As discussed below, these references are not combinable.

Daniel

Daniel is directed to distal protection filter devices and methods. The Examiner refers to two embodiments of Daniel that relate to expanding a distal protection filter device by mechanical actuation. As discussed below, in a vascular device, a filter is a structure that permits blood but not particulate to flow through the filter structure.

The first embodiment referred to by the Examiner is a distal protection device 122 shown in Figure 13A.

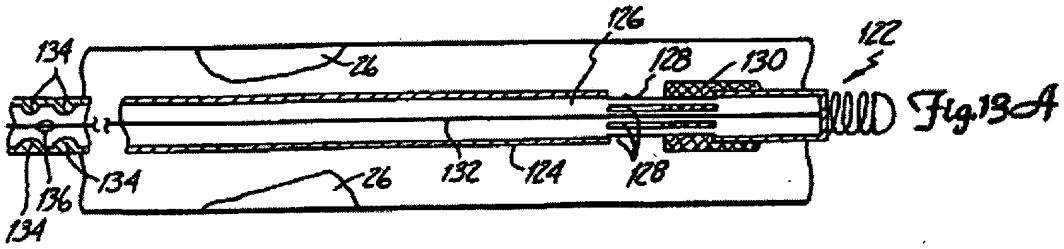


Fig.13A

The device 122 includes a slotted tube 124 which has a lumen 126 extending therethrough. The tube 124 has a plurality of slots 128 at a distal region thereof. The distal portion each of the slots 128 is covered by a flexible microporous membrane 130. A mandrel 132 extends through the inner lumen 126 of the tube 124 and is attached to the tube 124.

In use, the operator advances the tube 124 distally of a lesion to be fragmented and then pushes on the tube 124 and pulls on the mandrel 132 to deploy the device 122. The deployed position is shown in Figure 13B. In the deployed position, the microporous membrane 130 forms a filter assembly.

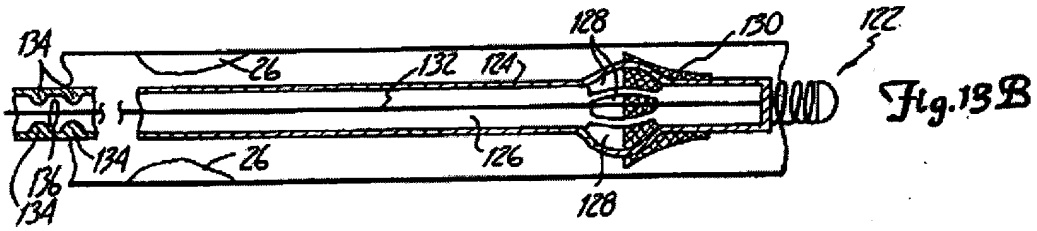


Fig.13B

The Examiner also refers to a distal protection device 140 illustrated in Figures 14A. In the device 140, struts 142 are formed of a metal or polymer material and are completely covered by a mesh 144.

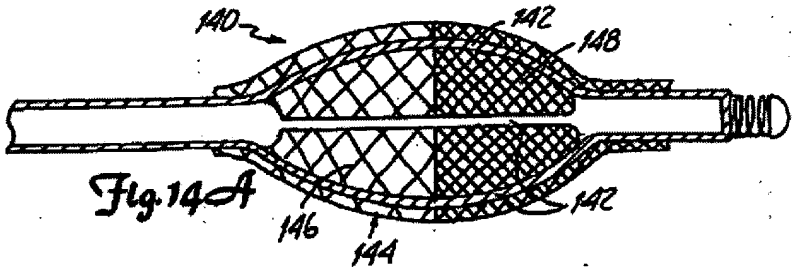


Fig.14A

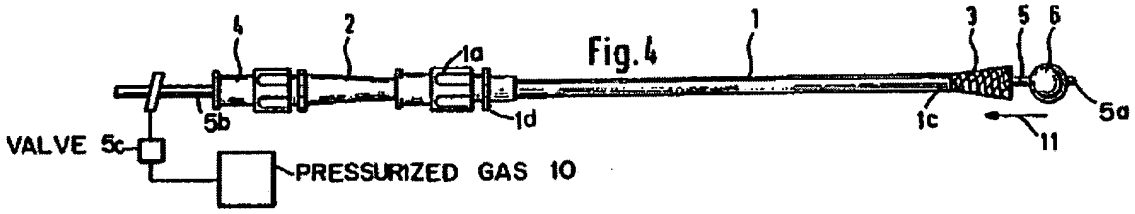
The mesh 144 includes a proximal portion 146 that is a relatively loose mesh that allows stenosis fragments to pass through and a distal portion 148 that is formed of a microporous membrane. The Examiner notes that the mesh portions can provide a memory set in the relaxed position. The device 140 is described as being "similar to that shown in FIGS. 13A and 13B." Column 8,

lines 51-52. Thus, the function of the distal portion membrane 148 is the same as the membrane 130 discussed above, to provide a filtering assembly to filter out stenosis fragments.

Although the reason for providing a filtering assembly is not explicitly stated in connection with the devices of Figures 13A and 13B and the embodiment of Figure 14A, the principle of operation of these devices is filtering and the intended purpose of these devices is to permit blood to flow distally of the filter while at the same time capturing particulate. A "filter" is defined elsewhere in the specification as a device that does not substantially interrupt the flow of blood through the filter. For example, in connection with the embodiment of Figures 1-4, Daniel states that a filter is formed that "allows blood to flow therethrough, but which provides a mechanism for receiving and retaining stenosis fragments carried into mesh 22 by blood flow through the vessel." Column 4, lines 48-50. Daniel uses similar language in connection with the embodiment of Figures 5-7 at Column 5, lines 45-49, with the embodiment of Figure 19 at Column 12, lines 13-16, with the embodiment of Figures 21A-21C at Column 14, lines 10-13, and with the embodiment of Figures 22A-22C at Column 16, lines 50-54. Thus, Daniel consistently teaches that distal protection devices should not fully occlude the vessel in which they are deployed, but should be specially configured to maintain blood flow through the filter.

Guenther

Guenther discloses a triple catheter for collecting and removing of blood clots from arteries and veins. See Figure 4 below.



The triple catheter includes an outer catheter 1 and an inner catheter 5. The inner catheter 5 has an inflatable balloon 6 at its distal end that can be inserted into the outer catheter 1. The inner catheter 5 is surrounded by an intermediate catheter 2 that is also inserted into the outer catheter 1. The intermediate catheter 2 has a radially expandable distal end funnel-shaped receptacle 3 made of an elastic mesh structure of spring wires or plastic monofilaments. Figure 4 illustrates that, in use, the receptacle 3 is deployed proximally of the area being treated. The receptacle 3 is covered by or embedded in an elastic coating. The coating of Guenther is

intended to prevent a blood clot from leaking through the receptacle 3. See column 2, lines 52-57.

The Combination Of Daniel And Guenther Is Improper

Applicants respectfully assert that a prima facie case of obviousness has not been made at least because the combination of Daniel and Guenther is improper.

The Examiner's rationale for combining Daniel and Guenther is improper because the proposed combination would change the principle of operation of the Daniel filter device and would render the Daniel filter device inoperable for its intended purpose. As discussed above, the Daniel distal protection filter device includes a filtering assembly, i.e., a structure that permits the passage of blood therethrough. This is directly contrary to the covering of Guenther, which is intended to prevent leaking of a blood clot through the receptacle 3. By adding the coating of Guenther to the filtering assembly of Daniel, the passage of fluids through the filter assembly would be severely restricted if not completely prevented. This modification would change the principle of operation of the Daniel distal protection filter, i.e., blood filtering wherein blood flow is not substantially interrupted. Adding the Guenther coating would prevent flow which would render the Daniel distal protection filter device inoperable for its intended purpose of capturing particulate while at the same time permitting blood to flow distally of the filter assembly. Thus, an improper rationale for the combination of Daniel and Guenther has been provided. See, e.g. M.P.E.P. §§ 2143.01 and 2145.

Additionally, the suggestion or motivation to combine is lacking. In assessing whether the prior art provides a motivation to combine, the reference must be considered in its entirety, including disclosure that teaches away from the claims. See, e.g., M.P.E.P. §§ 2141.02 and 2145. Here, the references teach away from the proposed combination. Daniel is directed to a device that filters blood, i.e., one that permits the passage of blood through the filter. See, e.g., Column 4, lines 48-50. Thus, Daniel teaches providing a structure distal of a stenosis that permits blood flow therethrough. Adding a cover that prevents blood flow to the Daniel filtering assembly would prevent filtering. Thus, Daniel teaches away from such a modification or combination.

Guenther does not provide a motivation to modify the filtering assembly of Daniel. Guenther is directed to a blood clot removal treatment and is not directed to providing distal

protection, as defined in Daniel. In Daniel, distal protection is provided by a filtering assembly that is positioned *distal of* a treatment location while a treatment is being performed. Stenosis fragments that are carried from the treatment location distally by blood flow are captured by the filtering assembly distal of the treatment location. In Guenther, the balloon 6 performs a treatment, which involves pulling a blood clot into the funnel shaped receptacle 3. Guenther does not teach or suggest providing a protecting structure distal of the balloon 6 to capture matter being conveyed by the blood; the balloon 6 is the distal-most structure.

Guenther fails to recognize the need to protect the patient from matter flowing distal of the balloon 6 and thus there is no distal protection as would be understood from Daniel. Because the funnel shaped receptacle 3 is located *proximal of* the treatment location (i.e., between the treatment site and the proximal portion of the Guenther apparatus) the teachings of Guenther relative to the receptacle 3 are not relevant to any modification of the filtering assembly of Daniel.

At least for the reasons stated above, an improper rationale for combining Daniel and Guenther has been proposed. Thus, a prima facie case of obviousness has not been made for Claims 43, 44, 48, 49, 51-56, and 58-64. Accordingly, Applicants respectfully request that the rejection of these claims be withdrawn and that these claims be allowed in the next Office Action.

Allowable Subject Matter

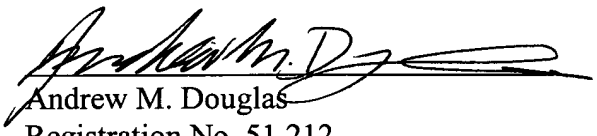
Applicants appreciate the Examiner's continued assertion that claims 45-47 would be allowable if rewritten in independent form.

CONCLUSION

In view of Applicants' amendments and remarks, Applicants respectfully submit that each of the pending claims is now in condition for allowance. Should the Examiner have any remaining concerns, the Examiner is invited to contact the undersigned at the telephone number appearing below.

Respectfully submitted,

Dated: May 4, 2005

By: 

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